Detailed Office Action

Status of the Claims

Acknowledgement is hereby made of receipt and entry of the communication filed 06 December, 2007. Claims 1-71 and 76-87 are pending in the instant application. Claims 1-52 and 80-83 are currently under examination. Claims 53-71, 76-79, and 84-87 stand withdrawn from further consideration by the examiner, pursuant to 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention. Applicants are reminded that a complete response to the final rejection must include cancellation of non-elected claims or other appropriate action (refer to 37 C.F.R. § 1.144 and M.P.E.P. § 821.01).

Objection to New Matter Added to Specification

The amendment filed 06 December, 2007, in response to the notice set forth under 37 C.F.R. § 1.821 through 1.825 is objected to under 35 U.S.C. § 132(a) because it introduces new matter into the disclosure. 35 U.S.C. § 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The amendment to the figure description asserts that SEQ ID NO.: 1 corresponds to the HR1 region. SEQ ID NO.: 1 corresopnds to the following amino acid sequence: NH2-Thr-Leu-Thr-...-Leu-Lys-Asp-Gln-Leu-Leu-**Gly-Ile**-COOH. The HR1 region set forth in Figure 1 has the following amino acid sequence: NH2-Thr-Leu-Thr-...-Leu-Lys-Asp-Gln-**Gln**-Leu-Leu-COOH. Bold-faced residues indicate a discrepancy between the sequence identifier and sequence set forth in the

figure. Applicant is required to cancel the new matter in the reply to this Office action.

37 C.F.R. § 1.821

As previously set forth, this application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. § 1.821 through 1.825 for the reason(s) set forth below Applicants are reminded that sequences appearing in the specification and/or **drawings** (see Figure 1) must be identified by a sequence identifier (SEQ ID NO.:) in accordance with 37 C.F.R. § 1.821(d). Sequence identifiers for sequences appearing in the drawings may appear in the Brief Description of the Drawings. Applicant must provide appropriate amendments to the specification and/or drawings inserting the required sequence identifiers. Extensive amendments may necessitate the submission of a substitute specification. As note in the preceding paragraph, the sequence referenced in the proposed amendment to the figure drawings does not match the sequence set forth in Figure 1. Applicants should carefully review the entire sequence listing for compliance.

35 U.S.C. § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode

contemplated by the inventor of carrying out his invention.

New Matter

Claims 1-36, 41, 43-50, 52, and 80-83 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *In re Rasmussen*, 650 F.2d 1212, 211 U.S.P.Q. 323 (C.C.P.A. 1981). Claims 1, 21, 29, 41, 43, 45, 47, 49, and 80 reference particular peptide size constraints (e.g., an amino acid sequence of **"greater than 36 amino acid residues"** from the HR1 region). Perusal of the disclosure failed to provide support for this particular limitation. The clear discussion of peptidic size constraints in the specification occurs at page 10 wherein it was stated that "no less than 16 and no more than 60 amino acids of the HR1 region" should be included. Additionally, it should be noted that some of the representative peptides set forth in the sequence listing and specification are precisely 36 amino acids in length. Thus, the skilled artisan would reasonably conclude that applicants were not in possession of the claimed invention at the time of filing. Appropriate correction is required.

Claims 4, 29, 30, 47, and 49 also reference specific mutations in the heptad repeat positions "$\mathbf{e_1f_2g_3a_4b_5c_6d_7e_8f_9}$". While there is a generic discussion in the specification of the HR1 region, support for these precise mutations could not be identified. Thus, the skilled artisan would reasonably conclude that applicants were not in possession of the claimed invention at the time of filing. Appropriate correction is required.

Claim Objections

Claims 6, 7, 8, 9, 10, 12, 14, 16, 18, 20, 23, 24, 26, 28, 31, 32, 34, 36, 38, 40, 42, 44, 46, 48, 50, 52, 81, and are objected to because of the following informalities: the phrase "comprising a component selected from the group consisting of one or more chemical group or moiety" should read --one or more chemical groups or moieties--. Appropriate correction is required.

35 U.S.C. § 112, Second Paragraph

The previous rejection of claims 1-36, 38, 40, 41, 43-50, 52, and 80-83 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is hereby withdrawn in response to applicants' amendment.

35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

The previous rejection of claims 1, 4, 11, 17, 29, 33, 41, 47, 49, 80, and 82 under 35 U.S.C. § 102(a) as being anticipated by Bewley *et al.* (2002), is hereby withdrawn in response to applicants' amendment.

35 U.S.C. § 103(a)

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 4, 11, 17, 29, 33, 41, 47, 49, 80, and 82

Claims 1-52 and 80-83, are rejected under 35 U.S.C. § 103(a) as being unpatentable over Bewley *et al.* (2002) in view of Barney *et al.* (1999). As set forth *supra*, Bewley and colleagues disclose synthetic peptides derived from the HR1 region of HIV-1 gp41 with potent antiviral activity. The peptides comprised one or more amino acid substitutions in the heptadic repeat (e.g., e_1, g_3, a_4, d_7, and e_8). It was also demonstrated that these polypeptides form trimeric structures in solution. This teaching does not provide all of the precise mutations claimed or various modifications to the polypeptide (i.e., the addition of reactive groups or carriers). However, this teaching clearly demonstrates that the HR1 region is a target for modification and provides several examples that produced peptides with desirable properties. Barney and associates also provide similar polypeptides with enhanced pharmacokinetic properties and disclose various peptidic modifications (i.e., the addtion of carriers or reactive groups). Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the

time of the invention to make additional mutations in the HR1 region, as described by Bewley *et al.* (2002), since this would result in the identification of additional polypeptides with the desired activities. All that is required is routine experimentation. It would also have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to make additional modifications to the polypeptides, as described by Barney *et al.* (1999), since this would produce synthetic polypeptides with enhanced pharmacokinetic profiles.

Applicants are reminded that a *prima facie* case of obviousness may be made when chemical compounds have very close structural similarities and similar utilities. See M.P.E.P. 2144.09. "An obviousness rejection based on similarity in chemical structure and function entails the motivation of one skilled in the art to make a claimed compound, in the expectation that compounds similar in structure will have similar properties." *In re Payne*, 606 F.2d 303, 313, 203 U.S.P.Q. 245, 254 (C.C.P.A. 1979). See *In re Papesch*, 315 F.2d 381, 137 U.S.P.Q. 43 (C.C.P.A. 1963) (discussed in more detail below) and *In re Dillon*, 919 F.2d 688, 16 U.S.P.Q.2d 1897 (Fed. Cir. 1991) (discussed below and in M.P.E.P. § 2144) for an extensive review of the case law pertaining to obviousness based on close structural similarity of chemical compounds. See also M.P.E.P. § 2144.08, paragraph II.A.4.(c). Compounds which are position isomers (compounds having the same radicals in physically different positions on the same nucleus) or homologs (compounds differing regularly by the successive addition of the same chemical group, e.g., by -CH2- groups) are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. *In re Wilder*, 563 F.2d 457, 195 U.S.P.Q. 426

(C.C.P.A. 1977). See also *In re May*, 574 F.2d 1082, 197 U.S.P.Q. 601 (C.C.P.A. 1978) (stereoisomers *prima facie* obvious). Applicants' arguments have been carefully considered but are not deemed to be persuasive. The claim amendments fail to distinguish over the prior art and the argument that it would have been "obvious to try" is not convincing. Since Bewley and colleagues have already demonstrated that modification of the heptadic repeats leads to polypeptides with favorable characteristics, it would only require routine experimentation to identify additional polypeptides.

The previous rejection of claims 1-52 and 80-83 under 35 U.S.C. § 103(a) as being unpatentable over Chan *et al.* (1997) in view of Barney *et al.* (1999), is hereby withdrawn in response to applicants' amendment and arguments.

35 U.S.C. § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Scope of Enablement

The previous rejection of claims 1-36, 40-52, and 80-83 under 35 U.S.C. § 112, first paragraph, because the specification does not reasonably enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these

claims, is hereby withdrawn in response to applicants' arguments.

Action Is Final, Necessitated by Amendment

Applicants' amendment necessitated any and all new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a). A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 10:30 AM to 9:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Bruce R. Campell, Ph.D., can be reached at (571) 272-0974. Direct general status inquiries to the Technology Center 1600 receptionist at (571) 272-1600. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

Applicants are reminded that the United States Patent and Trademark Office (Office) requires most patent related correspondence to be: a) faxed to the Central FAX number (571-273-8300) (updated as of July 15, 2005), b) hand carried or

delivered to the Customer Service Window (now located at the Randolph Building, 401 Dulany Street, Alexandria, VA 22314), c) mailed to the mailing address set forth in 37 C.F.R. § 1.1 (e.g., P.O. Box 1450, Alexandria, VA 22313-1450), or d) transmitted to the Office using the Office's Electronic Filing System. This notice replaces all prior Office notices specifying a specific fax number or hand carry address for certain patent related correspondence. For further information refer to the Updated Notice of Centralized Delivery and Facsimile Transmission Policy for Patent Related Correspondence, and Exceptions Thereto, 1292 Off. Gaz. Pat. Office 186 (March 29, 2005).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,

/Jeffrey S. Parkin, Ph.D./
Primary Examiner, Art Unit 1648

13 April, 2008